NOV 1 4 2003 **K031175 – Click'X Monoaxial System – Additional Information**

510(k) Summary of Safety and Effectiveness

Company: Synthes Spine Co., L.P.
1230 Wilson Drive
West Chester, PA 19380
(610) 647-9700

Proposed Proprietary Trade Name: Synthes Click'X Monoaxial System

Regulation Numbers: 888.3050, 888.3060 and 888.3070

Regulation Names: Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, Spondylolisthesis Spinal Fixation Device System, and Pedicle Screw Spinal System

Codes: NKB, KWP, MNH and MNI

Description:
The purpose of this submission is to incorporate additional Click'X Monaxial components into the Universal Spinal system. The Synthes Click'X Monoaxial system consists of a variety of shapes and sizes of rods, hooks, screws, transconnectors and connecting components. The Click'X Monoaxial implant materials are fabricated from commercially pure titanium or titanium alloy, conforming to ASTM F-67 or ASTM F-1295, respectively.

Indications:
The Synthes USS (including the Click'X and USS VAS variable axis components), Click'X Monoaxial, Dual Opening and the Small Stature USS (which includes small stature and pediatric patients) are non-cervical spinal fixation devices intended for use as a posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation systems (TI-L5), or as anterolateral fixation systems (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct.

When used with the 3.5/6.0-mm parallel connectors, the Synthes USS (including the Click'X and USS VAS variable axis components), Click'X Monoaxial and Dual Opening USS can be linked to the Cervifix system. In addition, when used with 3.5/5.0 mm parallel connectors, the Synthes Small Stature USS, can be linked to the CerviFix System. When used with the 5.0/6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS (including the Click'X and USS VAS variable axis components), the Click'X Monoaxial and Dual Opening USS Systems.

In addition, Synthes USS (including the Click'X and USS VAS variable axis components), Click'X Monoaxial and the Dual Opening USS can be interchanged with all USS 6.0mm rods and transconnectors.

Performance and SE Determination:
Comparisons of device performance data, materials, indications and design/function to predicate devices were provided in making a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Mr. John Walsh
Director, Regulatory/Clinical Affairs
Synthes Spine
1380 Enterprise Drive
West Chester, PA 19380

Re: K031175
Trade/Device Name: Synthes Click'X Monoaxial System
Regulation Number: 21 CFR 888.3050, 21 CFR 888.3060, 21 CFR 888.3070
Regulation Name: Spinal interlaminal fixation orthosis; Spinal intervertebral body fixation orthosis; Pedicle screw spinal system
Regulatory Class: Class II and Class III
Product Code: KWP, KWQ, MNH, MNI, NKB
Dated: August 20, 2003
Received: August 22, 2003

Dear Mr. Walsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031175 – Click'X Monoaxial System – Additional Information

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K031175

Device Name: Synthes Click'X Monoaxial System

INDICATIONS:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_
(Per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031175